K082095 P. 1/2

Endoscopy
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Andover, MA 01810

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We are smith+nephew

OCT 21 2008

SECTION IV

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Traditional 510(k) Submission of Smith & Nephew Ultraslide Acromioclavicular and Syndesmotic Repair Device

Date Prepared: ***July 22, 2008***

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover, MA 01810

B. Company Contact

Kathy Reddig

Regulatory Affairs Specialist II

978-749-1321 (Phone)

978-749-1443 (Fax)

kathy.reddig@smith-nephew.com

C. Device Name

Trade Name:	*Smith & Nephew Ultraslide Acromioclavicular and Syndesmotic Repair Device*
Common Name:	*Non-Absorbable Suture /Button Retention Device*
Classification Name:	*Single / multiple component metallic bone fixation appliances and accessories*

D. Predicate Devices

The Smith & Nephew Ultraslide Acromioclavicular and Syndesmotic Repair Device is substantially equivalent in design, indications and fundamental scientific technology to the following legally marketed devices in commercial distribution: Arthrex Tightrope™ Acromioclavicular (AC) Device (cleared via K052776) and the Arthrex Tightrope™ Syndesmosis Device (cleared via K043248).

E. Description of Device

The Smith & Nephew Ultraslide Device allows for endoscopic fixation following a syndesmotic trauma as Coracoclavicular Separations or Ankle Syndesmotic Disruptions. The device consists of three components: two machined titanium ENDOBUTTON fixation devices on a continuous Polyester suture loop. It is pre-threaded with a traction suture that is used for positioning of the fixation button. Although non-absorbable, the Ultraslide device does not require removal.

F. Intended Use

The Smith & Nephew Ultraslide Device is intended as an adjunct in fracture repair providing fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions or fixation of ankle syndesmosis due to anterior inferior tibiofibular ligament and/or posterior inferior tibiofibular ligament disruptions.

G. Comparison of Technological Characteristics

The Smith & Nephew Ultraslide Device is substantially equivalent in design and function to the currently marketed Arthrex Tightrope™. The proposed and the predicate devices both have the same indications and the same fundamental scientific technology.

H. Summary Performance Data

Statistical comparison of the test data of the cyclical displacement values and tensile strength demonstrates that there are no statistically significant differences between the Smith & Nephew Ultraslide Device and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
Endoscopy Division
% Ms. Kathy Reddig
Regulatory Affairs Specialist
150 Minuteman Road
Andover, MA 01810

OCT 21 2008

Re: K082095
Trade/Device Name: Smith & Nephew Ultraslide Acromioclavicular and Syndesmotic Repair Device
Regulation Number: 21 CFR 888.3030
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTN
Dated: July 22, 2008
Received: July 24, 2008

Dear Ms. Reddig:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082095

Device Name: Smith & Nephew Ultraslide Acromioclavicular and Syndesmotic Repair Device

Indications For Use:

The Smith & Nephew Ultraslide Acromioclavicular and Syndesmotic Repair Device is intended as an adjunct in fracture repair providing fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions or fixation of ankle syndesmosis due to anterior inferior tibiofibular ligament and/or posterior inferior tibiofibular ligament disruptions.

Prescription Use ___x_____ AND/OR Over-The-Counter Use ___N/a___

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhern

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082095